

### REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining be allowed.

#### Claim Amendments

Claims 25 and 34 have been canceled without prejudice or disclaimer.

New claims 39-52 have been added. Claims 39 and 46 are the same as canceled claims 25 and 34, respectively, except that the new claims are in independent form. Claims 40-45 depend from new claim 39 but otherwise correspond to claims 22, 23, and 26-29, respectively. Similarly, claims 47-52 depend from new claim 46, but are otherwise the same as claims 31, 32, and 35-38, respectively.

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting allowance of the claims and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

#### Rejection Under 35 U.S.C. §102

A. The rejection of claims 21-24 and 30-33 under 35 U.S.C. §102(e) over Cooper et al. (U.S. Patent No. 6,174,528, hereinafter "the Cooper patent") is respectfully traversed for the reasons set forth below.

The standard of anticipation under 35 U.S.C. §102 is that each and every element of the claim must be found in the cited reference. *In re Marshall* (CCPA 1978), 198 USPQ 344.

The Cooper patent does not teach each and every element of the claimed invention. Claim 21 of the present application is directed to a coiled-coil polypeptide comprising the formula  $(ab_i c_i d e f_i g_i)_n$ , where  $i=1,2,\dots,n$ , and  $n$  is at least three, said polypeptide being prepared by

- (a) selecting a solvent-accessible region of an epitope of a selected natural protein, wherein said region is not in a coiled-coil conformation in its native state, and inserting the amino acids from said region into the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions; and
- (b) independently inserting an amino acid selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, into each of the  $a$  and  $d$  positions such that the amino acids from the epitope in the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions are interrupted by the amino acids in the  $a$  and  $d$  positions;

wherein  $(ab_i c_i d e f_i g_i)_n$ , forms a coiled-coil.

Thus, the polypeptide of claim 21 is prepared by inserting amino acids from a pre-selected group into the  $a$  and  $d$  positions of the formula  $(ab_i c_i d e f_i g_i)_n$  and a solvent-accessible region into the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions. The solvent-accessible region is from an epitope of a natural protein, wherein the region is not in a coiled-coil conformation in its native state. Claims 22-24 depend from claim 21, thereby reciting all the elements of claim 21.

The Cooper patent teaches that one sequence can be embedded within a second sequence (see, for example, column 2, lines 19-21) to form a chimeric peptide. As correctly pointed out at page 3, lines 8-11 of the Office Action, the first and second sequences are derived from peptides, polypeptides or proteins having similar native conformation (column 2, lines 26-32 of the Cooper patent), and the second sequence folds to a coiled-coil conformation (column 2, lines 45-49 of the Cooper patent). Since the first and second sequences of the Cooper patent have similar native conformation, and the second sequence has a coiled-coil conformation, the native conformation of the first sequence is a coiled-coil as well. In contrast, the claimed invention requires that the inserted region is not in a coiled-coil conformation in its native state. Clearly, the Cooper patent does not teach each and every element of the claimed invention.

Applicants wish to point out that the Office Action tends to read the elements of the claimed invention into the reference, then concludes that the reference discloses the elements.

For example, the Office Action states at page 3, the third last line to page 4, line 3:

Further the reference teaches independently inserting an amino acid selected from within the sequence: LRRDLASREAKKQVEKALE (column 5, line 61 to column 6, line 23), this step is considered to disclose claim 21b and claim 30, which recite: selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, into each of the a and d positions. Thus anticipating claims 21 and 30. [sic]

This statement is incomprehensible. How could "independently inserting an amino acid selected from within the sequence: LRRDLASREAKKQVEKALE" be considered as disclosing "selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof, into each of the a and d positions"? In any event, the original text of the reference actually reads "a first amino acid sequence having at least three amino acids selected from within the following sequence: LRRDLASREAKKQVEKALE" (column 5, last five lines of the Cooper patent).

The Cooper patent also does not disclose each and every element of claim 30 or its dependent claims. Claim 30 is directed to a coiled-coil polypeptide, comprising an amino acid sequence represented by  $(ab_i c_i d e f g_i)_n$ , where

$i=1,2,\dots,n$ , and  $n$  is at least three;

$a$  and  $d$  are amino acids each independently selected from the group consisting of leucine, isoleucine, valine, phenylalanine, methionine, tyrosine, and derivatives thereof;

$(b_i c_i e f g_i)_n$  is a sequence of amino acids from a solvent-accessible region of an epitope from a selected natural protein, wherein said region is not in a coiled-coil conformation in its native state, and the sequence  $(b_i c_i e f g_i)_n$  is interrupted by amino acids  $a$  and  $d$  in

$(ab_i c_i d e f g_i)_n$ ; and

wherein  $(ab_i c_i d e f g_i)_n$  forms a coiled coil.

Thus, claim 30 also contains elements not disclosed by the Cooper patent, such as that  $(b_i c_i e f g_i)_n$  is derived from a region that is not in a coiled-coil conformation in its native state.

Claims 31-33 depend from claim 30, hence reciting all the elements of claim 30. Again, the Cooper patent does not teach each and every element of the claimed invention.

In view of the above, withdrawal of this rejection is respectfully requested.

**B.** The rejection of claims 21, 26, 28, 30, 35 and 37 under 35 U.S.C. §102(e) over Fishleigh et al. (U.S. Patent No. 5,773,572, hereinafter "the Fishleigh patent") is respectfully traversed for the reasons set forth below.

The Office Action states that the Fishleigh patent teaches a polypeptide that is 85.2% identical to SEQ ID NO:6 of the present application, thus alleging that the reference anticipates claims 21, 26, 28, 30, 35 and 37. Applicants disagree. This application does not claim SEQ ID NO:6. Instead, the claimed invention is a polypeptide comprising  $(ab_i c_i d e f_i g_i)_n$ , wherein the amino acids in the  $b_i$ ,  $c_i$ ,  $e_i$ ,  $f_i$  and  $g_i$  positions are derived from an epitope, such as those contained in SEQ ID NO:6. The claims clearly recite that "the sequence  $(b_i c_i e f_i g_i)_n$  is interrupted by amino acids  $a$  and  $d$  in  $(ab_i c_i d e f_i g_i)_n$ ". Therefore, the claimed polypeptide does not comprise SEQ ID NO:6, although certain embodiments comprise a sequence in which SEQ ID NO:6 has been modified at the  $a$  and  $d$  positions.

The Fishleigh patent does not disclose a polypeptide that comprises the required amino acids at the  $a$  and  $d$  positions, as well as a  $(b_i c_i e f_i g_i)_n$  sequence from a heterologous protein, as required in the claimed invention. Therefore, the reference does not teach each and every element of the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

**C.** The rejection of claims 21, 26, 28, 30, 35 and 37 under 35 U.S.C. §102(b) over Prusiner et al. (U.S. Patent No. 5,962,669, hereinafter "the Prusiner patent") is respectfully traversed for the same reasons as set forth above.

The Office Action states that the Prusiner patent discloses two sequences, part of which are 100% identical to SEQ ID NO:5 and SEQ ID NO:7, respectively. This is not surprising because SEQ ID NO:5 and SEQ ID NO:7 are sequences from prion proteins, which are the subject matter of the Prusiner patent. As discussed above, the claimed invention does not comprise SEQ ID NO:5 or SEQ ID NO:7. Rather, the present invention relates to the conversion of natural epitopes to coiled-coils. Thus, embodiments of the claimed invention may comprise sequences modified from SEQ ID NO:5 and SEQ ID NO:7, wherein the amino acids at the *a* and *d* positions are changed. Even if the Prusiner patent discloses SEQ ID NO:5 and SEQ ID NO:7, it does not disclose the present invention.

Accordingly, the standard under 35 U.S.C. §102 is not satisfied, and withdrawal of this rejection is respectfully requested.

#### Allowable Subject Matter

The Office Action indicates that claims 25, 27, 29, 34, 36 and 38 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim (page 5 of the Office Action). Claims 25 and 34 have been rewritten accordingly as new claims 39 and 46, respectively. Therefore, Applicants submit that claims 39 and 46, as well as their dependent claims (new claims 40-45 and 47-52), are in condition for allowance. Applicants further submit that all the other pending claims are also allowable in view of the reasons discussed above.

#### Conclusions

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections and objections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 839-5044.


Applicant : Kondejewski, et al.  
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Enclosed is a \$133.00 check for excess claim fees. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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